

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ZACHARY SILBERSHER, et al.,

Plaintiffs,

v.

ALLERGAN INC., et al.,

Defendants.

Case No. 18-cv-03018-JCS

**ORDER GRANTING MOTIONS TO
DISMISS**

Re: Dkt. Nos. 186, 187

I. INTRODUCTION

This action was brought under the federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, by Plaintiff-Relator Zachary Silbersher (“Relator”) on behalf of the United States and numerous States (the “States”)¹ against two sets of defendants: 1) the “Allergan Defendants” or “Allergan”²; and 2) the “Adamas Defendants” or “Adamas.”³ Each set of defendants brings a motion to dismiss (hereinafter, the “Allergan Motion” and the “Adamas Motion” and collectively, the “Motions”). The Court finds that the Motions are suitable for determination without a hearing and therefore **vacates the motion hearing set for March 17, 2023 at 9:30 a.m.** pursuant to Civil Local Rule 7-1(b). **The Case Management Conference set for the same date will be moved from 9:30 a.m. to 2:00 p.m.** For the reasons stated below, the Motions are GRANTED.⁴

¹ Relator brings this action on behalf of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.

² The Allergan Defendants are: Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. For purposes of this motion, the term “Allergan Defendants” does not include Defendant Allergan PLC, which has been dismissed from this action, even though references to “Allergan” in the operative complaint include Allergan PLC.

³ The Adamas Defendants are: Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc.

⁴ The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28

II. BACKGROUND

A. First Amended Complaint⁵

The operative complaint in this action is the First Amended Complaint (“FAC”). In the FAC, Relator alleges that the Adamas and Allergan Defendants misled the United States Patent Office (“Patent Office”) into issuing invalid patents protecting the drugs Namenda XR® and Namzaric®, thus perpetuating their monopoly power and allowing them to overcharge the federal government and the States for these drugs under various programs, including Medicare and Medicaid. FAC ¶¶ 1-8.

Relator is a citizen of the State of New York whose “profession focuses on investigating invalid pharmaceutical patents that brand manufacturers use to protect their drugs from price competition.” *Id.* ¶ 9. He alleges that he has “[t]hrough his independent investigation . . . uncovered non-public information supporting the claims set forth” in the FAC. *Id.* He further alleges that his “independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed allegations and transactions.” *Id.* According to Relator, he is an “original source” of information within the meaning of the FCA and he provided the information on which his claims are based to the States and the federal government before he initiated this action. *Id.* ¶ 10.

Relator alleges that Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. are subsidiaries or divisions of Allergan PLC, which was called Activas PLC until June 15, 2015. *Id.* ¶ 17. Activas PLC acquired Forest Laboratories, Inc. on July 1, 2014 and acquired Allergan, Inc. on March 17, 2015. *Id.* ¶¶ 17, 49. Relator alleges that “Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation with its principal place of business at Cumberland House, 1 Victoria Street, Hamilton HMU, Bermuda” and that “Allergan is the successor-in-interest to Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and is liable

U.S.C. § 636(c).

⁵ This section is taken verbatim from the Court’s December 11, 2020 Order on Defendants’ previous motion to dismiss, dkt. 135. It is included here for the convenience of the reader. The First Amended Complaint remains the operative complaint in this case.

1 for any damages to which Forest is liable.” *Id.* ¶ 16.⁶

2 Defendant Adamas Pharma, LLC is a Delaware limited liability company with its
3 principal place of business in Emeryville, California; Defendant Adamas Pharmaceuticals, Inc. is
4 a Delaware corporation, also based in Emeryville, California. *Id.* ¶¶ 18-19. According to Relator,
5 in 2012, Adamas Pharmaceuticals, Inc. entered into a commercialization and development
6 agreement with Forest Laboratories, Inc. with respect to memantine hydrochloride (“memantine”)
7 drugs. *Id.* ¶¶ 50, 59. Relator alleges that “[a]s part of that agreement, Adamas . . . granted Forest
8 an exclusive license to all of the Went Patents[,]” discussed below. *Id.*

9 Namenda XR® is a delayed-release drug whose active pharmaceutical ingredient (“API”)
10 is memantine. *Id.* ¶ 50. It is used to treat patients with dementia related to Alzheimer’s disease.
11 *Id.* According to Relator, generics of Namenda XR® first became available on February 21, 2018,
12 after the Federal Circuit invalidated patents asserted by Defendants in connection with that drug.
13 *Id.* Relator alleges that Allergan’s United States net revenue for Namenda XR® was
14 approximately \$452.8 million in 2017, \$627.6 million in 2016 and \$759.3 million in 2015. *Id.* ¶
15 52.

16 Namzaric® is also a delayed-release drug prescribed to treat patients with dementia related
17 to Alzheimer’s disease. *Id.* ¶ 53. It has two APIs: memantine hydrochloride and donepezil
18 hydrochloride. *Id.* ¶ 54. Relator alleges that “[g]eneric manufacturers have been ready to enter
19 the market since at least July 13, 2015, but they have been prevented from doing so by the
20 fraudulently-obtained patents asserted by Defendants” and that “[t]o date, no generic manufacturer
21 has entered the market for Namzaric®.” According to Relator, Allergan launched Namzaric® on
22 May 18, 2015; its net revenue for Namzaric® was approximately \$130.8 million in 2017, \$57.5
23 million in 2016 and \$11.2 [million] in 2015.” *Id.* ¶ 56.

24 Relator alleges that “Defendants listed three categories of patents for Namenda XR® and
25 Namzaric® in the [Food and Drug Administration (“FDA”)]’s database of “Approved Drug
26

27 ⁶ As noted above, the FAC defines “Allergan” as including Allergan, Inc., Allergan USA, Inc.,
28 Allergan Sales, LLC, Forest Laboratories Holdings, Ltd, and the now-dismissed Allergan PLC.
FAC at 1.

Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book[,]” thereby preventing generic manufacturer’s from entering the market. FAC ¶ 57.

The first category of patents is the Went Patents, a group of eleven patents that list Dr. Gregory T. Went, PhD., the founder and CEO of Adamas, as the first inventor.⁷ *Id.* ¶ 58. For Namenda XR®, six of the Went Patents are listed in the Orange Book (the ’209, ’708, ’379, ’752, ’085, and ’233 patents), while all eleven are listed for Namzaric®. *Id.* According to Relator, the Went Patents “are all generally directed to an extended release formulation for memantine.” *Id.*

The parent patent for all of the Went Patents is the ’291 patent, which was issued on November 15, 2011. *Id.* ¶ 61. Relator alleges that on June 21, 2010, during prosecution of the ’291 patent application, the Examiner issued an Office Action that rejected the pending claims as anticipated. *Id.* ¶ 62. In response, on November 5, 2010, Dr. Went and his co-inventors amended the independent claims of the ’291 patent application and submitted a declaration by Dr. Went (the “Original Went Declaration” or “2010 Went Declaration”) in which he discussed the results of two clinical studies conducted by Adamas, the C106 Study and the ME110 Study. *Id.* ¶ 63. Relator alleges that Dr. Went misrepresented the results of these studies in his declaration, asserting that they showed “no incidence” of certain side effects when in fact, the opposite was true. *Id.* ¶¶ 66-69, 73. According to Relator, on September 23, 2011, the Examiner allowed the claims based upon the alleged “unexpected results” sworn to by Dr. Went in this declaration. *Id.* ¶ 73.

Relator alleges that Dr. Went and Adamas continued to resubmit the same fraudulent data and did not correct these misrepresentations when applying for nine additional patents, misleading the Patent Office into granting the applications based on them. *Id.* ¶¶ 73-90. However, Relator alleges, during prosecution of U.S. Patent Application No. 12/757,824 (“the ’824 Application”),

⁷ The Went Patents are U.S. Patent Nos. 8,058,291 (“the ’291 patent”); 8,168,209, as corrected (“the ’209 patent”); 8,173,708 (“the ’708 patent”); 8,283,379 (“the ’379 patent”); 8,293,794 (“the ’794 patent”); 8,329,752 (“the ’752 patent”); 8,338,485 (“the ’485 patent”); 8,338,486 (“the ’486 patent”); 8,362,085 (“the ’085 patent”); 8,580,858, as corrected (“the ’858 patent”); and 8,598,233 (“the ’233 patent”).

on May 7, 2012, Dr. Went submitted another declaration (“the 2012 Went Declaration”) in which he again described the ME110 Study but provided a table of actual results and stated that they showed “little incidence” (rather than “no incidence”) of side effects with the extended release formulation. *Id.* ¶¶ 68-69. That application was rejected by the Examiner on the basis that the extended release formulation that it claimed did “not present better results in regards to side effects.” *Id.* ¶ 70. Adamas then abandoned that application. *Id.* According to Relator, Adamas continued to rely on the Original Went Declaration or slightly modified versions of that declaration that continued to misrepresent the results of the ME110 Study and the Examiner continued to allow the patents for the same reasons it allowed the ’291 patent. *Id.* ¶¶ 74-84.

The second “category of patents” listed for Namenda XR® and Namzaric® upon which Relator relies is a single patent, U.S. Patent No. 8,039,009 (“the ’009 patent”). *Id.* ¶ 91. Relator alleges that the ’009 patent was originally assigned to Forest Laboratories, Inc., and expires September 24, 2029.” *Id.* According to Relator, the ’009 patent is “directed to a method of treating Alzheimer’s disease with a once-daily sustained release oral dose of memantine.” *Id.* ¶ 92. Relator alleges that the application was amended to add the “once-daily” requirement after it had been rejected “at least six times” by the Patent Office, and based on this amendment the Patent Office allowed the ’009 patent. *Id.*

Relator alleges “[t]he once-daily limitation in the ’009 [p]atent is invalid as obvious in view of U.S. Patent No. 6,479,553 (“the ’553 [p]atent”), which expressly teaches treating Alzheimer’s disease by administering memantine once daily.” *Id.* ¶ 93. According to Relator, the ’009 patent was acquired by fraud because “Defendants were aware of the teachings of the ’553 patent, yet, on information and belief, Defendants intentionally failed to alert the Patent Office to the teachings of the ’553 patent when they amended the application for the ’009 patent to include the once-daily limitation.” *Id.* ¶¶ 93-94. Relator alleges that the ’553 patent had been disclosed during prosecution of the ’009 patent on September 28, 2009, but the disclosure was about 18 months before the amendment that required once-daily administration, on March 15, 2011, and therefore the once-daily teaching of the ’553 patent had no relevance to the ’009 patent application at that time and would not have been considered by the Examiner. *Id.* ¶ 96. Relator alleges that

1 “when Forest amended the application for the ’009 patent to require once-daily administration, it
2 intentionally declined to inform the Patent Office of the material relevance of the ’553 patent,
3 because the ’553 patent expressly taught the very limitation added to the claims . . . that justified
4 allowance of the ’009 patent.” *Id.* ¶ 97.

5 The “third category” of patents is U.S. Patent No. 5,061,703 (the ’703 patent”). *Id.* ¶ 4.
6 Because the parties have not relied on the allegations related to that patent in their briefs the Court
7 does not summarize them here.

8 Relator alleges that Defendants used the Went Patents and the ’009 patent to prevent
9 generic manufacturers from entering the market. *Id.* ¶¶ 104-109. “As a direct result of
10 Defendants’ fraudulent scheme, Defendants have unlawfully excluded generic manufacturers from
11 introducing lower-priced generic alternatives for Namenda XR® and Namzaric®, allowing
12 Defendants to charge monopoly prices.” *Id.* ¶ 110. Relator further alleges that for Defendants to
13 sell Namenda XR® and Namzaric® to federal agencies or otherwise qualify Namenda XR® and
14 Namzaric® for reimbursement under Medicare and Medicaid, they were required to list the drugs
15 on the Federal Supply Schedule (“FSS”) and “supply [to the General Services Administration
16 (‘GSA’)] a ‘written justification for offered pricing, a mechanism for 14 future potential pricing
17 adjustments, and proof that the price is fair and reasonable.’” *Id.* ¶¶ 112-113 (citation omitted).
18 According to Relator, “[b]y definition, Namenda XR®’s and Namzaric®’s pricing that Defendants
19 supplied in connection with the FSS was not fair and reasonable” because “Defendants . . . had
20 artificially inflated Namenda XR®’s and Namzaric®’s prices through the unlawful exclusion of
21 generic competitors” and therefore Defendants’ “statements to the GSA were expressly false
22 statements.” *Id.* ¶ 113. Relator further alleges that Defendants made “express and implied
23 misrepresentations that [their] prices were fair and reasonable – and not inflated through the
24 unlawful exclusion of competitors.” *Id.* ¶ 117.

25 Relator alleges that “each and every claim for payment or reimbursement for Namenda
26 XR® and Namzaric® that would have been substituted for a less expensive generic equivalent . . .
27 constituted a False Claim” that violated the federal FCA and the respective State false claims acts.
28 In particular, according to the Relator, “each False Claim was for an unlawfully elevated,

maintained, or stabilized price for Namenda XR® or Namzaric® contrary to express representations and implied certifications by Defendants to the federal government that the price of Namenda XR® or Namzaric® reflected in each False Claim was ‘fair and reasonable,’ and not unlawfully elevated, maintained, or stabilized in violation of applicable law, including applicable antitrust laws.” *Id.* ¶¶ 132-133.

B. Statutory Background

Under the FCA, any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” is liable for a civil penalty “plus 3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a)(1)(A)-(B). “The FCA allows private individuals, referred to as ‘relators,’ to bring suit on the Government’s behalf against entities that have violated the Act’s prohibitions.” *U.S. ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 569 (9th Cir. 2016) (citing 31 U.S.C. § 3730(b)(1)).

“As originally enacted, the FCA did not limit the sources from which a relator could acquire the information to bring a *qui tam* action.” *Graham County*, 559 U.S. at 295. Thus, in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (“*Hess*”), the Supreme Court “upheld the relator’s recovery even though he had discovered the fraud by reading a federal criminal indictment—a quintessential ‘parasitic’ suit.” *Id.* In response to the *Hess* decision and other similar “piggy-back” lawsuits, Congress enacted what came to be known as the “government knowledge bar,” which “preclude[d] *qui tam* actions ‘based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought.’” *Graham County*, 559 U.S. at 294 (citing Act of Dec. 23, 1943, 57 Stat. 609 (codified at 31 U.S.C. § 232(C) (1946 ed.))). After this change, the number of *qui tam* actions dwindled. *Graham County*, 559 U.S. at 294.

In 1986, Congress once again amended the FCA to make it “a “more useful tool against fraud in modern times[.]”” *Id.* (quoting *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 133 (2003) (quoting S.Rep. No. 99–345, p. 2 (1986))). The Senate Report that accompanied

the 1986 amendments stated that the purpose of the amendments was to address the “severe” problem of fraud against the federal government and pointed to the “proliferation of cases [of fraud against the government] among some of the largest Government contractors.” S. Rep. 99-345 at pp. 1-2. Among the changes enacted in 1986 was replacement of the government knowledge bar with the public disclosure bar. *Graham County*, 559 U.S. at 294 (“[A]pparently conclud[ing] that a total bar on *qui tam* actions based on information already in the Government’s possession thwarted a significant number of potentially valuable claims[,]” Congress replaced the government knowledge bar with the public disclosure bar in order to “strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits such as the one in *Hess*.”).

Following the 1986 amendment of the FCA, the public disclosure bar provided as follows:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). An “original source” was defined as “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” 31 U.S.C. § 3730(e)(4)(B).

In 2010, Congress amended the FCA again, as part of the Patient Protection and Affordable Care Act (“ACA”). *See* Pub. L. No. 111–148, § 10104(j)(2), 124 Stat. 119, 901–02 (“2010 amendments”). Among other things, the 2010 amendments reflected an effort by Congress to “fix[] the False Claims Act’s public disclosure provision . . . [to] fairly and appropriately empower whistleblowers to come forward to expose fraud, which is a crucial way to save the government money and ensure the health and well-being of Americans.” 155 Cong. Rec. S13661-01, 155 Cong. Rec. S13661-01 (daily ed. Dec. 21, 2009), S13693 (statement of Sen. Leahy).

As amended in 2010, the public disclosure bar now provides:

(4)(A) *The court shall dismiss an action or claim under this section,*

unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

(i) in a *Federal* criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, “original source” means *an individual* who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) *who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions*, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4) (amended language in italics).

C. Procedural Background

In response to the FAC, Defendants brought motions to dismiss seeking dismissal of Relator’s claims under the FCA’s public disclosure bar. *See* dkt. nos. 63, 68, 131. The undersigned found that under the FCA, as amended in 2010, the material elements of the allegedly fraudulent transactions upon which Relator bases his claims were publicly disclosed in the prosecution histories of the patents at issue in this case. *Silbersher v. Allergan Inc.*, 506 F. Supp. 3d 772, 799 (N.D. Cal. 2020), rev’d and remanded sub nom. *United States v. Allergan, Inc.*, 46 F.4th 991 (9th Cir. 2022). The Court concluded, however, that these disclosures were not made “through one of the channels that triggers the public disclosure bar under the FCA” because patent prosecutions are not “Federal . . . hearing[s]” for the purposes of the public disclosure bar. *Id.* at 800. Therefore, the Court concluded that the public disclosure bar did not apply and did not reach the question of whether Relator qualified as an “original source” under 31 U.S.C. § 3730(e)(4)(B).

Recognizing that its order denying Defendants’ motions to dismiss “addressed difficult questions of first impression with respect to the significance of recent amendments to the FCA, and [that] it ha[d] reached different conclusions from another judge of this Court” on similar claims, the Court granted Defendants’ motion to certify the order for immediate appeal. Dkt. no.

147. The Ninth Circuit, in turn, granted Defendants’ petition to bring an interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Dkt. no. 149.

On appeal, as in this Court, Relator argued that the public disclosure bar did not apply to his claims because the patent prosecution history was not a “hearing” for the purposes of the public disclosure bar. Silbersher Br. at 23-26, *U.S. ex rel. Silbersher v. Allergan, Inc.*, No. 21-15420 (9th Cir. Aug. 27, 2021) (“*Silbersher* Appellate Brief”). He argued further that even if it was, he was an “original source” under the FCA because following the 2010 amendments, “direct” knowledge of the alleged fraud was no longer required and he met the two remaining requirements, namely, that he had knowledge that was “independent” of and “materially add[ed]” to the public disclosures. *Id.* at 26. In support of this assertion, he pointed to his “personal subject-matter expertise” and “specialized knowledge of the relevant patent prosecution histories, prior art, and regulatory regime[,]” which he argued was both “independent” of the allegations and transactions upon which this case is based and “materially add[ed]” to the public disclosures. *Id.* at 72-73.

On August 25, 2022, the Ninth Circuit reversed the decision of this Court, finding that a patent examination is a “Federal ... hearing” under the second prong of the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A)(ii). *United States v. Allergan, Inc.*, 46 F. 4th 991, 999 (9th Cir. 2022). The Court of Appeals did not reach the question of whether Relator was an “original source” under the FCA, remanding the case to this Court to address that question. *Id.* at 1000.

D. The Motions

1. The Allergan Motion

In its motion, Allergan rejects Relator’s argument that “he qualifies as an original source because he used his ‘specialized knowledge’ of ‘the ways that drug patents, approvals, and prices’ interact to uncover the purported fraud.” Allergan Motion at 6 (quoting *Silbersher* Appellate Brief at 73). According to Allergan, the Ninth Circuit and every other court of appeals to consider the issue, has “repeatedly rejected the notion that using ‘expertise’ to ‘formulate [a] novel legal theory of fraud’ makes a relator an original source.” *Id.* (citing *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000)).

Even following the 2010 amendments to the FCA, Allergan asserts, it is still the rule that “specialized expertise or background knowledge that helps the relator piece together a fraud claim” is not sufficient to make a relator an original source. *Id.* (citing *Roe v. Stanford Health Care*, 2022 WL 796798, at *1 (9th Cir. Mar. 15, 2022); *U.S. ex rel. Hastings v. Wells Fargo Bank, NA*, 656 F.App’x 328, 331-32 (9th Cir. 2016); *U.S. ex rel. Jones v. Sutter Health*, 499 F.Supp.3d 704, 718 (N.D. Cal. 2020)). According to Allergan:

The 2010 amendments eliminated the requirement that the relator possess “direct” (i.e., “firsthand”) knowledge of the information on which the allegations are based—making clear that secondhand knowledge can suffice too. But Congress did not change the kind of “knowledge”—i.e., “substantive information about the particular fraud, rather than merely background information which enables a putative relator to understand the significance of a publicly disclosed transaction or allegation . . . —that one must provide the government to qualify as an original source.

Id. at 7 (citing *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991)).

In support of its assertion that the current version of the FCA, like the pre-2010 version, requires a relator to come forward with “historical facts about the alleged fraud[,]” Allergan points to the “ordinary meaning of ‘original source[,]’” arguing that “the phrase ‘original source’ is most naturally understood to refer to someone who supplies new historical facts” such as “[w]histleblowing insiders, people who provide information to reporters, and anonymous tipsters[.]” *Id.* at 7-8. Moreover, Allergan argues, Section 3730(e)(4)(A) “specifies that a relator must be an ‘original source of the information’ . . . and the Supreme Court has held that the phrase refers to ‘information underlying the allegations of the relator’s action.’” *Id.* at 8 (emphasis added in Allergan’s brief) (quoting *Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 472 (2007)). This understanding finds further support in the second half of the original source definition, Allergan asserts, requiring that “the relator must ‘provide[] the information to the Government before filing an action.’” *Id.* at 8 (quoting 31 U.S.C. §3730(e)(4)(B)). According to Allergan, “[u]nlike whistleblowers who share with the government what they learned on the inside, or those who learn of facts about the defendant’s conduct from an insider, Silbersher cannot ‘provide’ his ‘expertise’ or ‘deep familiarity’ with patent law to the government.” *Id.*

Allergan also cites the “Ninth Circuit’s long-standing interpretation of the phrase ‘independent knowledge’ (which Congress left untouched in the 2010 amendments)[,]” which it contends reinforces its position. *Id.* at 9. In particular, the Ninth Circuit has held that “independent knowledge” must precede the public disclosure – a requirement that “makes sense only if what the relator must know is historical facts underlying the fraud.” *Id.* (citing *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 705 (9th Cir. 2017); *Malhotra v. Steinberg*, 770 F.3d 853, 860 (9th Cir. 2014)).

Allergan also rejects Silbersher’s reliance at the Ninth Circuit on “a letter sent by Senator Grassley and Representative Berman to the Attorney General in 1999 and a 2008 Senate Report to support his position.” *Id.* (citing *Silbersher* Appellate Brief at 6-7, 29-31 (citing 145 Cong. Rec. E1546 (1999), S. Rep. 110-507 (2008))). As to the letter, Allergan contends “[t]he remarks of two legislators more than a decade earlier carry no weight at all.” *Id.* (citing *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 298 (2010) (finding same letter “of scant or no value” in interpreting 1986 bar)). As to the 2008 Senate Report, Allergan points out that that report “did not even accompany the 2010 amendments; it accompanied the False Claims Act Correction Act of 2007, S. 2041, 110th Cong., 1st Sess. (2007), a bill introduced by Senator Grassley that Congress never passed.” *Id.* at 9-10.

Finally, Allergan argues that even if specialized knowledge were sufficient to qualify Relator as an original source, he has “failed to plausibly allege that he supplied any.” *Id.* at 10. According to Allergan, “Silbersher’s complaint never explains exactly what ‘specialized knowledge’ he purportedly used or how. Nor does it explain how his knowledge ‘materially adds to’ what is in the public domain. Silbersher just conclusorily alleges that his ‘independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed allegations and transactions.’” *Id.* (quoting FAC ¶ 9). Allergan further asserts that Silbersher should not be given leave to amend his complaint because amendment would be futile. *Id.* at 10 n. 3. In particular, it argues that “a relator cannot become an original source by pointing to his ‘expertise[]’ [a]nd Silbersher has admitted that he does not possess any material non-public facts about the alleged fraud.” *Id.* (citing December 19, 2019 Hearing Tr. 9:15-20,

50:6-12).

2. The Adamas Motion

Adamas's arguments mirror the arguments made in Allergan's Motion. Like Allergan, Adamas argues that even after the 2010 amendments to the FCA, a relator's specialized expertise is not sufficient to make them an original source and that even if it were, Relator here has not alleged any specific facts that make his allegations plausible.

E. Oppositions

In his Opposition briefs, Relator sets forth six categories of information he says he provided to the government as an original source:

- (1) Dr. Went's November 5, 2010 declaration was false or misleading, and the true results of the referenced ME110 study undermine Defendants' reliance on another study also cited in the patent applications, the C106 study. (Complaint, ¶¶ 85-88)
- (2) The '553 Patent became newly relevant to the application for the '009 Patent after the latter application was amended to require a once-daily limitation that had already been taught in the '553 Patent, such that the omission of the '553 Patent after amendment was a materially misleading omission. (Complaint, ¶¶ 96-98)
- (3) The '553 Patent must be considered prior art based on the calculated priority date for the '009 Patent. (Complaint, ¶ 95)
- (4) The misstatements in Defendants' patent applications were intentional. (Complaint, ¶¶ 68-83)
- (5) The Went Patents and the '009 Patent were the key patents preventing each of the 16 potential generic competitors from entering the market based on the validity or invalidity of any, some, or all of the thirteen listed patents in the Orange Book.
- (6) The false and misleading statements in Defendants' patent applications tainted each of the relevant patents, which directly resulted in excluding specific competitors from the market.

Dkt. no. 189 ("Allergan Opposition") at 2; *see also* dkt. no. 188 ("Adamas Opposition") at 8-10.

According to Relator, the six categories of information described above satisfy the requirements of the original source exception set forth in 31 U.S.C. § 3730(e)(4)(B) because they constitute "knowledge" that is "independent of" and "materially adds to" the publicly disclosed information in the patent prosecution history. Allergan Opposition at 3; Adamas Opposition at 6-8.

He contends his reading of the FCA's language finds support in the context in which the 2010 amendments to the FCA were enacted as well as the purpose of the statute. Allergan Opposition at 3-6.

III. ANALYSIS

A. Legal Standards Under Rule 12(b)(6)

A complaint may be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim on which relief can be granted. "The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint." *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). Generally, a plaintiff's burden at the pleading stage is relatively light. Rule 8(a) of the Federal Rules of Civil Procedure states that a "pleading which sets forth a claim for relief . . . shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a).

In ruling on a motion to dismiss under Rule 12(b)(6), the court analyzes the complaint and takes "all allegations of material fact as true and construe[s] them in the light most favorable to the non-moving party." *Parks Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal may be based on a lack of a cognizable legal theory or on the absence of facts that would support a valid theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A complaint must "contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562 (2007) (citing *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "[C]ourts 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Twombly*, 550 U.S. at 555 (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557) (alteration in original). Rather, the claim must be "'plausible on its face,'" meaning that the plaintiff must plead sufficient factual allegations to "allow[] the court to draw the reasonable

inference that the defendant is liable for the misconduct alleged.” *Id.* (quoting *Twombly*, 550 U.S. at 570).

B. Is Relator an Original Source?

The Court previously found that “substantially the same . . . transactions as alleged in [Relator’s] action or claim were publicly disclosed” under § 3730(e)(4)(A) because “the prosecution histories of the patents at issue in this case disclose the material elements of the fraud that is the basis for Relator’s claim, both with respect to the Went Patents and the ’009 patent, as they reveal both the true and false state of affairs with respect to the alleged fraud.” Dkt. no. 135 at 32. While Relator has pointed to various categories of information he contends were *not* contained in the prosecution histories (listed above), all of them amount to conclusions he drew from analyzing the prosecution history using his specialized expertise in patent law; they do not change the Court’s conclusion that the public patent files disclosed the transactions that Relator alleges were fraudulent. Indeed, Relator conceded at the hearing on the previous motion to dismiss that the patent files contain “the relevant information from which the inference of fraud could be drawn.” Dkt. no. 116 at 9:15-20. Further, the Court of Appeals found that a patent examination is a “Federal . . . hearing” under the second prong of the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A)(ii). Consequently, Relator’s claims fail under the public disclosure bar unless he qualifies as an “original source.” The Court finds that he does not.

Under the case law construing the pre-2010 version of the FCA, it was established in the Ninth Circuit that an “original source” did not include a relator who “‘merely uses his or her unique experience or training to conclude that the material elements already in the public domain constitute a false claim.’” *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000) (quoting *United States ex rel. Findley v. FPC–Boron Employees’ Club*, 105 F.3d 675, 688 (D.C.Cir.1997)). The court in *A-1* explained:

[T]he public disclosure bar is triggered by disclosure of “allegations or transactions.” 31 U.S.C. § 3730(e)(4)(A). “A relator’s ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed.” *United States ex rel. Findley v. FPC–Boron Employees’ Club*, 105 F.3d 675, 688 (D.C.Cir.1997).

1 *Id.* Relator asserts, however, that this authority is no longer good law in the wake of the 2010
2 amendments modifying the FCA’s definition of “original source.” According to Relator, to the
3 extent that a relator’s specialized expertise “materially adds to the publicly disclosed allegations or
4 transactions” it is now sufficient to qualify him as an original source.

5 As discussed above, under the FCA following the 2010 amendments, an “original source”
6 is defined as “an individual who . . . has knowledge that is independent of and materially adds to
7 the publicly disclosed allegations or transactions, and who has voluntarily provided the
8 information to the Government before filing an action under this section.” 31 U.S.C. §
9 3730(e)(4)(B). To understand the type of “knowledge” that may qualify a relator as an “original
10 source” under this definition, the Court applies two related canons of construction. First, ““unless
11 otherwise defined, words [are] interpreted as taking their ordinary, contemporary, common
12 meaning.”” *Sandifer v. U.S. Steel Corp.*, 571 U.S. 220, 227 (2014) (quoting *Perrin v. United*
13 *States*, 444 U.S. 37, 42 (1979)). Second, “[t]o discern that ordinary meaning, those words must be
14 read and interpreted in their context, not in isolation.” *Sw. Airlines Co. v. Saxon*, 142 S.Ct. 1783,
15 1788 (2022) (internal quotations and citations omitted).

16 The most straightforward change in the original source language under the 2010
17 amendments is the removal of the requirement that the relator’s knowledge must be “direct.” This
18 Court agrees with Judge Tigar’s conclusion that “the removal of the word ‘direct’ appears to
19 broaden the exception and permit a relator to qualify as an ‘original source’ of information even if
20 that information was obtained indirectly.” *United States v. Kiewit Pac. Co.*, 41 F. Supp. 3d 796,
21 807 (N.D. Cal. 2014). Congress did not, however, drop the requirement that a relator’s knowledge
22 must be “*independent of*. . . the publicly disclosed allegations or transactions.” 31 U.S.C. §
23 3730(e)(4)(B) (emphasis added). In *Amphastar Pharms. Inc. v. Aventis Pharma SA*, the Ninth
24 Circuit held that knowledge is “independent” if the relator had “relevant ‘evidence of fraud prior
25 to the public disclosure of the allegations.’” 856 F.3d at 705. Under this definition, a relator whose
26 knowledge of the alleged fraud is derived from applying their specialized expertise to the facts that
27 have *already* been publicly disclosed in sources enumerated in § 3730(e)(4)(A) cannot claim to
28 have “independent” knowledge under the “original source” exception. While *Amphastar*

1 interpreted the pre-2010 version of “original source,” the Court finds nothing in the amended
2 definition to suggest that the meaning of “independent” has changed.

3 The Court’s conclusion finds further support in the reference in both the pre- and post-
4 2010 versions of the FCA to the “information” that an original source must have “voluntarily
5 provided . . . to the Government” to qualify as an “original source.” The Supreme Court,
6 interpreting the earlier version, found that this “information” is the “information underlying the
7 allegations of the relator’s action.” *Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 472
8 (2007). The Court’s ruling in *Rockwell* supports the conclusion that the word “information” in the
9 definition of “original source” refers to the historical facts relating to the alleged fraud rather than
10 any specialized expertise the relator brought to bear in order to discern those facts. This is also
11 the most natural reading of this word – and one that is consistent with the Court’s understanding of
12 the “independent” knowledge requirement. The Court further notes that the requirement that a
13 relator disclose this “information” to the government before filing suit would make little sense if
14 the “information” the relator was required to provide the government before filing suit was their
15 specialized expertise.

16 Relator focuses heavily on the requirement that an original source’s knowledge must
17 “materially add[] to the publicly disclosed allegations or transactions[.]” pointing to the State of
18 California’s statement that it “welcomes the efforts of Relators like Mr. Silbersher” because there
19 is no “government agency that regularly monitors patent filings to determine whether there has
20 been a material omission or misrepresentation in applications for pharmaceutical patents,
21 particularly given the specialized expertise and amount of resources that would be required to do
22 so.” Allergan Opposition at 6 (citing dkt. no. 133). The problem with Relator’s argument is that it
23 ignores language in the amended definition, discussed above, indicating that Congress did not
24 expand the definition of an original source so broadly as to encompass the type of knowledge that
25 Relator brings to bear in this case. Likewise, while there are certainly statements in the legislative
26 history suggesting that some legislators would have liked to expand the definition to the extent
27 Relator proposes, that is not, in fact, where Congress drew the line in attempting to encourage
28 private individuals to root out fraud while stifling “parasitic” lawsuits.

Finally, although there is no binding authority on the question, both the Ninth Circuit (in unpublished decisions) and this Court have concluded that under the post-2010 definition of “original source[,]” specialized expertise does not “materially add to public disclosures.” *See Roe v. Stanford Health Care*, 2022 WL 796798, at *1 (9th Cir. Mar. 15, 2022) (“specialized expertise” does not “materially ad[d]” to public disclosures); *U.S. ex rel. Hastings v. Wells Fargo Bank, NA*, 656 F.App’x 328, 331-32 (9th Cir. 2016) (“background information . . . did not materially add to what [the government] already knew”); *U.S. ex rel. Jones v. Sutter Health*, 499 F.Supp.3d 704, 718 (N.D. Cal. 2020) (same).

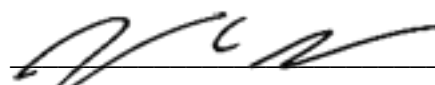
For the reasons stated above, the Court finds that Relator is not an original source and that his claims against all Defendants are therefore barred under the public disclosure bar and must be dismissed.⁸

IV. CONCLUSION

The Motions are GRANTED. Because Relator’s complaint cannot be cured by amendment, the case is dismissed with prejudice as to both Allergan and Adamas.

IT IS SO ORDERED.

Dated: March 13, 2023


JOSEPH C. SPERO
Chief Magistrate Judge

⁸ Because the Court finds that the theory underlying Relator’s assertion that he is an “original source” fails as a matter of law, it does not reach Defendants’ argument that Relator failed to allege specific facts regarding the specialized expertise he claims allowed him to uncover the fraud he alleges in the complaint.